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Medical Device Excise Tax: Impact on Manufacturers and Hospitals as Repeal Efforts Continue

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On January 29, 2013, the first semi-monthly payment of approximately $97 million was collected by the IRS from medical device companies under a new excise tax ("MDET"). Since then, the IRS has collected an additional $291 million, according to Advamed, an industry group. The MDET was established to generate revenue to support programs enacted under the Affordable Care Act ("ACA") and is anticipated to raise approximately $29 billion over 10 years. Medical device manufacturers have launched an aggressive campaign to repeal the tax, often citing the negative effect it may have on innovation, investment in new medical technologies and job growth. In fact, as a result of this strong opposition, on March 21, 2013, the Senate voted overwhelmingly in favor of repealing the MDET. Many have characterized this vote as symbolic since the vote is non-binding and part of the Senate's continuing efforts towards budget resolution. Repeal efforts have been slow to gain traction because there is a legitimate concern that the anticipated revenue generated from this tax could not be realized elsewhere to help fund the ACA. Thus, since the MDET has yet to be repealed, the pressing question is whether manufacturers will pass through this tax via increased prices or an added line item to purchasers (e.g., health care providers).

BACKGROUND

On December 5, 2012, the IRS issued final regulations to implement the MDET, accompanied by Notice 2012-77, which addresses deferred issues from the final regulations. Effective January 1, 2013, the MDET requires manufacturers, producers and importers ("taxpayers") to pay a 2.3% excise tax on the gross sales of taxable medical devices as defined in Section 201(h) of the Federal Food, Drug & Cosmetic Act ("FFDCA"). Most medical devices intended for humans and used or implanted by providers are taxable, including loaned or leased equipment, equipment used in medical or clinical research and sales contracts for software and IT systems classified as medical devices. Additionally, the MDET requires bi-monthly deposits from taxpayers.

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To avoid penalties, taxpayers must deposit at least 95% of their net tax liability incurred during the period unless the following safe harbor applies. Some devices are not subject to the MDET, including the sale of eyeglasses, contact lenses and hearing aids. This "retail exemption" is available where (i) a device is regularly available for purchase and personal use by individual consumers, and (ii) the device's design shows that it is not primarily intended for use in a medical institution or by a medical professional. The FDA uses a "facts and circumstances" approach to determine whether a device falls within the retail exemption; the final regulations list non-exclusive factors to assist in making this determination. Additionally, the final regulations provide a safe harbor provision that states that certain medical devices are always subject to the retail exemption without regard to the facts and circumstances analysis. For example, the safe harbor applies to certain medical devices that are purchased by the general public for personal use (e.g., over-the-counter devices and durable medical equipment, prosthetics, orthotics and supplies (Medicare Part B) not requiring professional insertion).

OTHER HIGHLIGHTS OF THE FINAL REGULATIONS AND THE RELATED INTERIM GUIDANCE INCLUDE:

Sales by Persons Other Than the Manufacturer. If title to, or ownership of, a taxable device passes from the manufacturer to a transferee, like a distributor, then the MDET attaches to the sale of the device by the transferee to the same extent and manner as if the transferee were the manufacturer of the device. Contract manufacturers are not subject to the MDET, except when specifications developers provide the manufacturing materials and retain title, which is not a common arrangement in the medical device manufacturing industry. The easiest way to differentiate the contract manufacturer from the taxable manufacturer is to determine who the FDA-registered manufacturer is for that device.

Parts and Replacement Parts. Because the definition of "taxable medical device" is tied to the FDA's listing requirements for devices, then associated devices, components and parts registered with the FDA as medical devices are also taxable. This may result in disparate treatment of parts depending on the manufacturers' marketing choices. For example, a diagnostic X-ray tube housing sold as a stand-alone replacement part and labeled for medical use must be registered with the FDA and is therefore taxable. However, the same product sold only as a replacement component to an imaging system may not need to be registered with the FDA and could avoid the tax. Whether or not the product is registered with the FDA is often a strategic marketing decision by the manufacturer. If a device is replaced under warranty, the taxable price of the replacement article is the amount paid, if any, to the manufacturer.

Leases. Leases are taxable. Medical imaging original equipment manufacturers are especially concerned as many of their products are capital equipment and often leased. However, the tax only applies to contracts entered into or materially modified on or after January 1, 2013.

Convenience Kits. Convenience kits (defined as a set of two or more devices packaged in a single bag, tray or box for the convenience of a provider) are taxed based on the individual devices within the kit. For domestically produced kits, the MDET is imposed on the sale of the taxable devices going into the kits. For imported kits, the MDET is imposed on the sale of the kit by an importer but only on that portion of the sales price allocable to taxable medical devices within the kit. Hospitals or medical institutions that produce kits for their own use are not manufacturing or producing a taxable medical device under the MDET.

Software. Software and software upgrades not listed with the FDA as medical devices under the FFDCA are not taxable. Examples of listed software and IT systems include medical device data systems and certain mobile medical applications. If listed software is packaged with a non-listed device, such as a smartphone, only the software is taxable. Similarly, software services contracts are not taxable, so when listed software is bundled with service, the tax should be based on only the sale price properly allocable to the software. The IRS has also proposed treating a license of listed software as a lease of a taxable medical device as of the date both parties entered into the license agreement.

Determination of Taxable Price. There are a number of costs that can be deducted from the sales price on which the MDET is charged. For example, it appears that containers, packing, transportation, delivery, insurance and installation costs may be deductible from the taxable price. However, there is little definitive guidance on determining taxable price because the IRS acknowledges existing Internal Revenue Code rules and guidance do not squarely apply to health care product supply chains.

IMPACT ON HEALTH CARE PROVIDERS

The ACA does not prohibit manufacturers from recouping the MDET costs from customers. As a result, the looming question has been: "How will the industry respond to the MDET?" Given the MDET's recent effective date, we are just beginning to see how manufacturers, servicing entities and health care providers are managing it. According to the Health Care Supply Chain Association, more than 45 device manufacturers have informed hospitals that they intend to pass the cost of the MDET on to providers. Generally speaking, it is the small manufacturers that have started passing on some or all of the MDET costs to customers;

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larger manufacturers have indicated they intend to lower production costs before passing on the costs.

While hospitals, long-term care facilities and other health care providers will not be directly responsible for the MDET, recent reports suggest that some medical device manufacturers are now shifting the burden of the tax onto their provider customers. Hospitals and group purchasing organizations ("GPOs") are already receiving invoices and billing notices with line-items explicitly referencing the MDET as an additional cost or a general price increase on a product. Of note, if the manufacturer adds the MDET as a line-item, it cannot be described as a tax on the customer because it is a tax on the manufacturer. Several manufacturers have been chastised for passing the MDET to their customers through a line-item addition and have reversed their positions.

As an alternative, manufacturers may attempt to recoup the MDET by raising their product prices. Raising prices without specifically calling out the MDET could potentially avoid the public shaming and boycotts that customers and GPOs are driving. This price increase will result in a higher tax paid by the manufacturer but will likely be the approach favored by most sellers. Market analysts suspect hospitals are already seeing vendors "bake it into the contract renewals." However, unless a product's cost increases by exactly 2.3%, it may be difficult for purchasers to spot cases where manufacturers are raising prices to cover the MDET. The medical device industry has seen significant increases in costs of utilities, gasoline, raw materials and employee health care, as well as other costs from multiple regulations, such as the Sunshine Act, MDET collection, unemployment insurance and state and local taxes.

CONTRACT CONSIDERATIONS

Providers should be aware of this potential for cost-shifting by medical device manufacturers and modify agreements to make clear that the provider will not be responsible for the MDET. Current contracts should be analyzed to identify pertinent language regarding cost increases. New contracts should include terms preventing line-items, stating that the purchaser will not be liable for any taxes related to the supplier's income, revenues, corporate characteristics, the MDET or other supplier-related excise taxes. Terms establishing fixed prices and scheduled price increases provide an additional layer of protection. Furthermore, purchasing through GPOs may prevent most MDET pass-throughs as GPOs are at the forefront in trying to prevent manufacturers from doing so. Providers should consult with their GPOs or legal counsel to avoid liability for the excise tax. ■

Physician Payment Sunshine Act Final Rule Released

On Friday, February 1, 2013, the Centers for Medicare and Medicaid Services ("CMS") published the final rule implementing the Physician Payment Sunshine Act ("Act"). The Act requires drug, biological and medical device manufacturers ("Applicable Manufacturers") to annually disclose payments they make to Covered Recipients when the payments are related to Covered Products.

Covered Recipients include teaching hospitals, doctors of medicine and osteopathy, dentists, podiatrists, optometrists and chiropractors, but not physician-residents or employees of manufacturers. Covered Products include any drug, device, biological or medical supply for which payment is available under Medicare, Medicaid or Children's Health Insurance Program (either separately or as part of a bundled payment). Covered Products must also be a drug or biological that requires a prescription to be dispensed or a device that requires premarket approval or premarket notification from the FDA.

The Act requires manufacturers and group purchasing organizations to disclose ownership and investment interests held by Covered Recipients and their immediate family members. These disclosures will be published by CMS to a website that the general public can access.

There are several practical takeaways for health care entities associated with the Act:

Manufacturers – Manufacturers should evaluate whether they must comply with the law by:

- Determining if they make or hold title to any products that meet the definition of Covered Products; and
- Identifying any financial relationships with Covered Recipients, especially as related to those Covered Products.

Commonly-Owned Entities – Any entity that shares a corporate structure or joint venture with another entity that manufactures or refurbishes medical products, takes title to such products or is registered with the FDA as the product's manufacturer should:

- Determine whether the manufacturing entity is an Applicable Manufacturer;
- Classify the nature of support given to the Applicable Manufacturer (critical or non-critical); and
- Identify any payments made to Covered Recipients.

Health Care Providers – The Act does not impose reporting obligations on health care providers; however, it promotes transparency that may expose providers to heightened scrutiny by the government pertaining to the False Claims Act, Stark Law, Anti-Kickback Statute, federal regulations on conflicts in clinical research and patient injury lawsuits involving the safety of medical devices or drugs. Physicians and teaching hospitals that may be Covered Recipients should establish internal procedures to track their own information and regularly review CMS's publicly reported data. ■

Regulatory Implications of Bundled Contractual Arrangements

EXECUTIVE SUMMARY

Many proposed contractual arrangements involve the vendor offering discounted or free medical equipment on the condition that the purchaser buy a certain percentage of its requirements of other products from that vendor ("Proposals"). These Proposals often contain language that suggests they meet the requirements of the Discount Safe Harbor ("DSH") of the Anti-Kickback Statute ("AKS"), and are thus a protected arrangement not subject to enforcement action under the AKS.

The AKS makes it a criminal offense to knowingly and willfully solicit, receive, offer or pay remuneration, directly or indirectly, overtly or covertly, in cash or in kind, in exchange for, or to induce the referral of, any item or service for which payment status may be made in whole or in part under the federal health care programs ("Programs"). The DSH is one of several exceptions to this general rule. Careful consideration should be given as to whether these Proposals can meet the DSH.

ANALYSIS OF PROPOSALS AS A "DISCOUNT"

Discounts for health care items are generally encouraged, provided that Programs appropriately share in the discount. Notably, however, "discount" does not include supplying one good without charge or at a reduced charge to induce the purchase of a different good, unless the goods are reimbursed by the same Program and the reduced charge is fully disclosed.

In response to concerns that Proposal-like arrangements would be prohibited, the Office of Inspector General of the U.S. Department of Health and Human Services ("OIG") confirmed that the DSH includes all permissible discounts. The OIG has also stated that such practices are permissible when the goods discounted are reimbursed by the same Program using the same methodology. A Proposal that satisfies these requirements will be protected by the DSH and will involve little or no risk of being subject to AKS enforcement.

If the DSH requirements are not met, the Proposal could pose a higher risk of AKS noncompliance depending on the facts and circumstances. The preambles to the DSH Final Rules and the relevant OIG Advisory Opinions support the proposition that if the DSH does not apply to a particular Proposal, the OIG may consider enforcement action, taking into account the parties' intents, the amount of benefit and whether it was disclosed and whether the goods are separately reimbursable, among other factors.

Many Proposals do not qualify as "discounts" under the DSH because the equipment and products are not reimbursable by the same Program or because the arrangements do not satisfy the factors discussed in the relevant OIG Advisory Opinions, which are viewed as paramount in proving the parties' intents.

ANALYSIS OF PROPOSALS AS A "REBATE"

The DSH defines "rebate" as any discount, the terms of which are fixed and disclosed in writing to the buyer at the time of the initial purchase to which the discount applies, but which is not given at the time of sale. The OIG has consistently stated that a rebate can only be applied to the same good that was purchased, and a rebate obtained on the purchase of one good cannot be used toward the purchase of a different good.

In assessing the potential AKS implications of advance contractual payments, such as up-front rebates, the OIG concluded that the DSH would not apply because such payments are made prior to any purchase and are not attributable to identifiable purchases of items. Such arrangements make proper disclosure difficult and "lock in" purchasers, which risks overutilization.

Thus, even assuming that the Proposals meet the definition of a discount, they still risk being likened to an up-front rebate and deemed suspect under the AKS. This is particularly applicable where payment is not required if the purchaser fails to meet purchase requirements. Therefore, careful review of such Proposals under the AKS is recommended. ■

Quarterly Check-Up

Opportunities for Pharmacies and Long-Term Care Facilities in the New DEA Proposed Rule for Controlled Substance Disposal, but What about Hospitals? On December 21, 2012, the Drug Enforcement Agency released an important proposed rule governing the secure disposal of unused controlled substances. The proposed disposal processes are intended to facilitate the safe return of controlled substances in response to growing concerns regarding the diversion and abuse of unused controlled substances.
http://tinyurl.com/a96a6uw

OIG Advisory Opinion 12-20: OIG Permits Hospital to Provide Free Access to Electronic Interface to Physicians. On December 19, 2012, the OIG posted an Advisory Opinion permitting hospitals to provide physicians, free of charge, an electronic interface that would enable the physicians to transmit orders for lab and diagnostic services to the hospital and to receive the results of such services.
http://tinyurl.com/aq3m7fk

Estate Planning Insights – January 10, 2013. This Estate Planning Insights audio alert discusses the new tax Act approved by Congress and its three primary changes to federal estate and gift tax laws. **http://tinyurl.com/a63bjsq**

Tax-Exempt Hospital Organizations Must Give Careful Attention to Proposed Regulations Under Code Section 501(r) – But When Must They Come Into Full Compliance? In addition to completing their first community health needs assessments by the end of the current tax year, hospital organizations now face detailed and complicated proposed regulations that will govern the other aspects of Code Section 501(r), including financial assistance policies, limitations on charges and billing and collection practices.
http://tinyurl.com/as3wjet

Alina Health DSH Case Implications: DSH Payments and 340B Eligibility. In November 2012, the Federal District court of the District of Columbia issued a decision favorably affecting disproportionate share hospital ("DSH") patient percentage calculations. If the decision is upheld on appeal, Medicare Advantage days may be removed from the SSI/Medicare Fraction of the DPP calculation, which would typically increase the DSH patient percentage. **http://tinyurl.com/bh42b7j**

HIPAA Impact Series. Hall Render's HIPAA Impact Series has provided in-depth analysis of HIPAA issues and developments since the passage of HITECH and the recently released HITECH Final Rule. To view the HIPAA Impact Series, visit **www.hallrender.com/hipaa**.

The Flu and Mandatory Flu Shots – The Employer's Dilemma. If a hospital or other health care entity has a mandatory flu vaccine program or is considering implementing a program, it must carefully consider all of the legal implications. Employers should develop a process that will carefully and consistently evaluate each request in order to properly meet their obligations to the public as well as to the employees who serve the public. **http://tinyurl.com/agjgs95**

FMLA Final Regulations Finally Issued – New Poster Required March 8, 2013. On February 6, 2013, a Final Rule was issued, requiring, among other things, a new FMLA poster, reflecting many of the changes made by the new regulations, to be posted in the workplace.
http://tinyurl.com/atcyz5s

Qui Tam Ruling May Result in Part D Sponsors and Pharmacy Benefit Managers Increasing Their Audit Activities. On December 20, 2012, a Federal District Court judge allowed a False Claims Act case to continue against a Pharmacy Benefits Manager related to the services it furnished to an unrelated Medicare Part D Sponsor.
http://tinyurl.com/bgpqagv

You Can Share a Governing Board but Not a Medical Staff: Medicare Proposes Changes to Hospital Conditions of Participation. On February 7, 2013, CMS issued a proposed rule that addresses a number of changes to the Conditions of Participation for hospitals, including changes relating to governing boards and the medical staff.
http://tinyurl.com/b5wfgwo

CMS Proposes Additional Changes to Regulations Impacting CLIA Certified Laboratories, ASCs, Long-Term Care Facilities and ICF/IIDs. On February 7, 2013, CMS released a proposed rule that would revise the Conditions of Participation and Conditions for Coverage for a variety of health care providers and suppliers, as well as certain regulations under CLIA. The deadline for submitting comments was April 8, 2013.
http://tinyurl.com/b5g3nnm

Things to Consider as You Are Considering a Business Acquisition. When considering a business acquisition, it is important to think about reviewing the potential target before the purchase is consummated and conducting due diligence reviews of the target.
http://tinyurl.com/cqtxdh6

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TO VIEW HALL RENDER'S ARTICLES visit our website at **www.hallrender.com/articles.**
For additional information regarding supply chain issues, please review the following articles and look for upcoming alerts on product shortages and recalls, excluded providers and more.

- Off-Label Use of Medical Products: Warranty and Indemnification Considerations in Purchase Agreements
- HRSA Extends GPO Exclusion Guidance Compliance Deadline from April 7, 2013 to August 7, 2013
- OIG Releases Physician-Owned Entity Special Fraud Alert
- CMS Publishes the Final Physician Payment Sunshine Rule
- Final Sunshine Rule Requires Reporting of Physician Ownership in GPOs and Health Products Manufacturers

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